DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

November 13, 2003

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 04-10

Mr. Benjamin A. Cutler, President
Genesis Juice Cooperative
325 West 3rd Avenue, Suite B
Eugene, Oregon 97401

WARNING LETTER

Dear Mr. Cutler:

We inspected your firm, located at 325 West 3rd Avenue, Suite B, Eugene, Oregon, on August 20, 2003, and found that you have serious deviations from the Juice Hazard Analysis Critical Control Point (HACCP) regulations (21 CFR Part 120). These deviations cause the100% lemon juice, used in your finished lemonade products; your 100% unpasteurized, "organically grown", apple juice; your unpasteurized, "organically grown" fresh raw carrot combo juice, made from 100% carrot, beet, celery, and wheat grass juice; and your other 100% juices to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the juice HACCP regulations through links in FDA's home page at www.fda.gov. Your firm is a small business and therefore you were to be in compliance with this regulation by January 21, 2003, as required by 21 C.F.R. § 120.1.

The deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 120.8(a). However, your firm does not have a HACCP plan for the unpasteurized 100% lemon juice (used in your finished lemonade products); the

unpasteurized 100% apple juice; the unpasteurized carrot combo juice (made from 100% carrot, beet, celery, and wheat grass) to control the food safety hazard of pathogens, or any other hazards reasonably likely. Furthermore, your firm does not have a written Hazard Analysis to determine whether there are food safety hazards that are reasonably likely to occur, and to identify control measures that you can apply to control those hazards, for your unpasteurized 100% lemon juice, unpasteurized 100% apple juice and the unpasteurized 100% combo juice that you process.

2. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 120.6(c). However, your firm did not maintain sanitation control records for the following:

   (a) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;
   (b) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
   (c) Prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;
   (d) Maintenance of hand washing, hand sanitizing, and toilet facilities;
   (e) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
   (f) Proper labeling, storage, and use of toxic compounds;
   (g) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
   (h) Exclusion of pests from the food plant.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

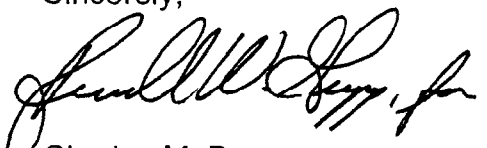
Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plans for your 100% juice products, copies of

Sanitation Standard Operating Procedure records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and the Current Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have questions regarding any issue in this letter, please contact Michael J. Donovan at (425) 483-4906.

Sincerely,



Charles M. Breen
District Director

Enclosure:
Form FDA 483

cc: OSDA, with disclosure statement